

JUN 21 2000

**510(k) Summary for
Behring Coagulation Timer™ Analyzer**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001064

1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
Marburg/Germany

Contact Information: Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714
Attn: Rebecca S. Ayash

Preparation date: May 26, 2000

2. Device Name/ Classification:

Behring Coagulation Timer™ Analyzer: Multipurpose system for *in vitro*
Coagulation studies

Classification Number: Class II (864.5425)

3. Identification of the Legally Marketed Device:

Behring Coagulation System™ Analyzer (BCS™) [K992959]

4. Device Description:

The current BCT™ Analyzer was determined to be substantially equivalent as a fully automated photometric coagulation analyzer in 510(k) Premarket Notifications K955278. The current BCT™ Analyzer was cleared to perform coagulometric, and chromogenic tests, such as the routine tests prothrombin time, partial thromboplastin time, heparin, derived fibrinogen and fibrinogen, as well as the special tests, single factor determination, antithrombin IIIa, batroxobin, plasminogen, protein C, and von Willebrand factor. The inclusion of the new testing parameter D-dimer, and immunochemical measuring method, is the subject of this modification. The modified BCT™ Analyzer has the ability to perform coagulometric, chromogenic and immunochemical assays (e.g., latex enhanced turbidimetric test Advanced D-Dimer).

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5. Device Intended Use:

The Behring Coagulation Timer™ Analyzer (BCT™) is an automated blood plasma coagulation analyzer for *in vitro* diagnostic use.

6. Medical device to which equivalence is claimed and comparison information:

The modified BCT™ Analyzer is substantially equivalent in intended use and results obtained to the BCS™ Instrument, which was the subject of 510(k) Premarket Notification K992959. Both instruments use photometric technology at various wavelengths for the measurement of a variety of coagulometric, chromogenic, and immunochemical assays.

7. Device Performance Characteristics:

Correlation:

The modified BCT™ Analyzer comparison study evaluated 113 plasma samples ranging from 0.46 to 38.7 mg/l on BCT™ Analyzer with the Advanced D-Dimer assay versus BCS™ Analyzer with the Advanced D-Dimer assay. A correlation coefficient of 0.996 was obtained, with a y-intercept value of -0.29 and a slope of 1.09. Please find the correlation graph and data as Attachment 7.

Precision:

Precision studies were performed by the evaluation of one level of normal human plasma, two levels of human pathological pools and two levels of control material in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 2.2 to 5.0%, while the intra-assay precision ranged from 1.7 to 5.9%.

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rebecca S. Ayash
Manager, Regulatory Affairs, Biology
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: K001064
Trade Name: Behring Coagulation Timer™ Analyzer
Regulatory Class: II Product Code: JPA
 II GHH
Dated: May 26, 2000
Received: May 30, 2000

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

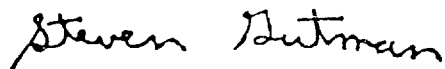
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K001064

Indications Statement

Device Name: Behring Coagulation Timer™ Analyzer

Indications for Use:

The Behring Coagulation Timer™ Analyzer (BCT™) is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

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|---|------------------------|
| •Prothrombin Time (PT) | •Fibrinogen |
| •Activated Partial Thromboplastin Time (APTT) | •Heparin |
| •Antithrombin IIIa | •Plasminogen |
| •Batroxobin | •Protein C-clotting |
| •D-dimer | •Protein C-chromogenic |
| •Deficient Plasmas | •Thrombin Time |
| •Derived Fibrinogen | •von Willebrand factor |

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K001064

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter-Use
(Optional Format 1-2-96)